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SUBCOMMITTEE ON HOMELAND SECURITY

REGARDING
BIODEFENSE AND PANDEMIC INFLUENZA PLANNING

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Chairman Gregg, Senator Byrd, and Members of the Committee, it is an honor for me to testify before you today regarding my views on the state of biodefense and pandemic planning in the United States.

Just over one year ago, I had the honor to testify before you and this Committee on the state of implementation of the Project BioShield Act of 2004 and the need for liability protections to promote participation in the biodefense market, but also to stimulate development of influenza pandemic countermeasures. Since that time, significant progress has been made.

In the area of biodefense, the Department of Health and Human Services (HHS) has acquired 10 million doses of a safe and effective FDA licensed anthrax vaccine from BioPort Corporation to better prepare the Nation against another anthrax attack like the one suffered by this body in October 2001. In addition, HHS has announced that the long-awaited purchase of anthrax therapeutics for post-exposure treatment of anthrax victims will be completed very shortly.

From a policy standpoint, Deputy Secretary Alex Azar recently announced that he and Secretary Leavitt are about to complete a revised implementation strategy for Project BioShield to eliminate many of the delays that have been observed in the BioShield program. Given the substantial talents of Deputy Secretary Azar, his personal involvement in this effort is welcome and encouraging.

Of course, reintroduction of legislation by Senator Burr, with the Chairman's co-sponsorship, creating the Biomedical Advanced Research and Development Agency (BARDA), and the commitment by the President in his FY 2007 budget to fund such an effort with nearly $200 million, is a very positive development. Creation of BARDA will go a long way to address the "valley of death" in biodefense countermeasure development and merits the strong support of industry for passage this year.

In the area of research and development for pandemic vaccines, recent events have also been very positive. On May 3, 2006, Secretary Leavitt announced the award of almost $1 billion in advance development contracts for cell-culture influenza vaccines. These contracts are milestone driven, and support multiple companies pursuing diverse technologies. Given the recent challenges HHS has faced with its contractor, VaxGen, for an experimental anthrax vaccine being developed under BioShield, it is clear that HHS understands the need not put its eggs in one basket with influenza countermeasures.

We should also take heart in the size and diversity of the companies awarded the cell-culture contracts. From successfully engaging a large company like GlaxoSmithKline, to making awards to innovative biotechnology companies like

MedImmune - which has developed the first licensed innovation in flu vaccine technology in over 50 years with its FluMist vaccine - it is clear that HHS has made substantial progress over the last year. HHS is now moving forward with development of adjuvant technology to improve the disappointing effectiveness of the H5N1 vaccine purchased last year, as well as to continue development of exciting new vaccine technologies such as DNA-based vaccines and novel antivirals. At the same time, HHS has recognized the need to accelerate the development of critical rapid diagnostics, and has announced plans to move forward with an advance development program for such technology in the coming weeks.

But perhaps most importantly, under your leadership, Mr. Chairman, as well as the leadership of Majority Leader Frist and Senator Burr in the Senate, and Speaker Hastert, Congressman Lewis, and Congressman Issa in the House, on December 30, 2005, President George W. Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act).

Through this legislation, the United States Congress has provided a key tool to protect the nation from infectious disease and other threats that could potentially cripple the U.S. and the global economy. As a result of the PREP Act, vaccine and countermeasure developers are now better protected from the mass of lawsuits that have basically eviscerated the U.S. vaccine and countermeasure manufacturing base, leaving it ill prepared for threats such as avian influenza. With the implementation of these strategic and valuable protections, the U.S. is now in a far better position to revitalize its domestic capability to produce the tools needed to secure the health and well-being of its citizens.

In short, the PREP Act offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use and other activities so that the protections can be applied as broadly as possible.

This law dramatically improves the ability of the United States to develop the tools it needs to be prepared for a naturally occurring or terrorist-related public health emergency. However, it is absolutely critical for HHS take the necessary steps now to implement fully the PREP Act, as intended by Congress and the President, to prepare the Nation for a influenza pandemic. To that end, industry eagerly awaits the Secretary's declaration of a potential public health emergency for an influenza pandemic, thereby triggering the protections of the PREP Act for covered countermeasures. In addition, industry looks forward to the release of the

regulations required by the Act to provide further clarity on the scope of the Act and its protections.

However, will all the outstanding progress the United States has made over the last year, both in the area of biodefense and pandemic planning, more can, and must, be done.

First, I would urge Congress to consider providing incentives to private entities to better prepare for a pandemic. A recent study by Mercer Human Resource Consulting has estimated that only 7% of U.S. companies have established budgets for pandemic preparedness, compared with 12% for European companies and 25% for Asian businesses. The private sector must take the lead in properly preparing for a pandemic threat, not only for their own businesses, but also, for the communities where they operate, and not rely upon government to prepare the Nation on its own.

Pandemic preparedness is first and foremost an issue of public health. But it is also an issue of ensuring American competitiveness in the global markets. If we are less prepared than the rest of the World, not only will our Nation's health suffer more, but so will our economy and our path to recovery from such an event. Companies must plan now for the possibility that 40% or more of their work force may not be able to show up to work during a pandemic, including, according to a recent study by the Johns Hopkins Bloomberg School of Public Health, up to 67% of back office health care workers providing technical support, payroll and payment processing, and other administrative functions. Public companies, of course, have an even greater obligation to implement internal controls to address such an event to assure that shareholder assets are protected and their business recovers as quickly as possible.

To that end, Congress should act now to consider changes in policy similar to those passed to prepare the Nation for the Y2K threat. This includes providing additional incentives, such as expanded liability protections, to those entities that make reasonable and prudent efforts to prepare for a pandemic. Congress should provide, at a minimum, the same level of protections provided by Congress on a bipartisan basis in the Y2K Act of 1998, signed by President Clinton.

Policy changes to improve telework and increase high-speed internet access should also be part of this effort. The Administration's pandemic plan recommends that employers keep employees three feet apart in a pandemic event. Given that more and more companies are enabling employees to work remotely, perhaps Congress should provide incentives now to ensure that telework options are widely available. With sufficient bandwidth and data security to operate with large numbers at the same time, workers could work safely from home, thereby stemming spread of the pandemic while reducing the economic impact.

To the greatest degree possible, we must also ensure that certain critical functions for maintaining the operations of our health care infrastructure can be automated or operated remotely in those circumstances. Thus, Congress should expedite passage of legislation promoting electronic medical records as soon as possible.

The Y2K legislation served as a national wake up call to Americas businesses and gave them the comfort of liability protection to identify and correct the problems with their IT infrastructure. Many businesses then (like many hospitals, health insurers, and other businesses critical to our nation's health care infrastructure today), were afraid to even explore their vulnerabilities for fear of creating a paper trail for eager trial lawyers to launch baseless lawsuits in the future. U.S. businesses, particularly those critical to our health care infrastructure, need a similar wakeup call - and equal liability protection - to upgrade, test, and retest our public health infrastructure to ensure pandemic readiness. Like with Y2K, even if a pandemic worst case scenario never happens, providing the legal certainty for businesses to upgrade their infrastructure and adequately prepare will improve our Nation's fragile health care system - leading to better patient care, lower costs, fewer medical mistakes, and better patient privacy. It is truly a win-win scenario.

Second, we must examine the supply chain for delivery of critical countermeasures that must be deployed during a pandemic, as well as the supply chain for delivery of good and services, as a whole, during a state of emergency caused by a pandemic. Most certainly, some - if not all borders - will close during a pandemic, thereby crippling food distribution and delivery of critical goods and component parts made outside of the United States. For critical countermeasures, Congress should deal now with policies to ensure protection from counterfeiting and theft of public health supplies. Congress should encourage the private sector to pursue implementation of workable, non-burdensome tracking mechanisms, while ensuring the protection of data and other information needed to allow the supply chain to function.

Because timing is essential, the federal government should rely on the expertise and experience of the private sector in developing and executing mission-critical functions like supply chain management and inventory control. We should ensure that policies encourage implementation of commercially tested systems – preferably those already in place in key parts of the health care infrastructure, that can be quickly and easily implemented. Effective supply chain management solutions for the strategic stockpiles must be proven and reliable, and be able to link thousands of stakeholders including pharmaceutical and medical supply companies, health care providers, distributors, shippers, security and customs organizations, and private and public local, state, federal and international health care agencies.

Effective supply chain management may also require considerable automation, since significant numbers of personnel throughout the supply chain may be sick or fail to show up for work. Information must also, to the greatest degree possible, be readily accessible, but yet secure, among multiple jurisdictions. In addition, the communication channels must be easily interoperable with multiple existing systems using different levels of technical standards and training of operating personnel.

Finally, Congress must act now to implement policies that will bolster our fragile public health infrastructure, and especially, our hospital system. Should a pandemic strike the Nation, the surge on the hospitals, nationwide, both from patients who are actually sick with influenza or another illness, as well as the "worried well," will cripple our Nation's healthcare system unless we are fully prepared. Addressing a *U.S. News & World Report* meeting on health and preparedness, Secretary of Homeland Security Michael Chertoff noted that hospitals, nursing homes, and other health facilities "have a *legal and moral obligation* to develop evacuation plans and other emergency plans to ensure that people with special needs whose care has been entrusted to these caregivers will, in fact, be taken care of and will get the appropriate care in an emergency." We must give these entities the tools they need to meet this legal and moral obligation.

Under the best of circumstances, emergency response workers may receive a vaccine that provides some level of immunity prior to a pandemic, and thus, will have some small degree of protection. However, the hospital administrators, claims processors, and support personnel are unlikely to receive any vaccine in time. With hospital support staff either at home to avoid illness, or already sick, while the hospitals are being pummeled by acute care patients, no claims will be processed to insurers. Thus, hospitals will be under significant financial strain, potentially unable to recover, and likely will be taken over by the Federal government, as has already occurred in some of the areas impacted by Katrina.

In addition, painfully hard triage decisions on who will receive care, and when they receive it, are certain to lead to baseless lawsuits unless some protections from liability are provided to health care providers. Trial lawyers are already lying in wait, planning their litigation strategies around the occurrence of such an event. The last thing the Nation will need during a flood of illness is a flood of lawsuits - Congress should act now to stem the tide of such an event.

In terms of other policy changes that would benefit overall preparedness for a pandemic, the United States has the opportunity to build the infrastructure today to support improved access to influenza vaccine and better immunization for annual influenza - which kills over 30,000 American each year. Expanded immunization recommendations for influenza vaccine, particularly among the young who drive disease transmission, should be strongly considered. Congress

should also challenge healthcare providers and the public health system to not squander the opportunity to begin building and testing the influenza vaccine infrastructure within the framework of current immunization recommendations. Policymakers should act quickly to accelerate those recommendations, including universal pediatric vaccination up to 18 years of age, in order to build as much vaccine infrastructure capacity as possible to better prepare the Nation for a pandemic without the expenditure of any additional Federal dollars. The bottom line is that we should build out the vaccine infrastructure with a seasonal flu approach, which will, in turn, not only protect the population today for the annual flu strain, but also allow us to look for any leaks that might sink the ship under the wave of a pandemic flu crisis.

Turning briefly to the implementation of Project BioShield, while implementation has been improved, and according to HHS, additional improvements are under way, more can be done. When I last testified before you in April 2005, I noted that the regulations mandated under Project BioShield had yet to be promulgated. Unfortunately, that is still the case today. I also noted that the material threat assessment (MTA) process conducted by the Department of Homeland Security under BioShield provided neither the speed nor the clarity necessary to allow the full promise of BioShield to "build a market" to materialize. While some improvements have been announced in the MTA process, industry has seen little evidence that this problem has been adequately addressed. For example, when I testified last year, I noted that the market for badly needed countermeasures for cyanide – a well known and clearly established threat – was uncertain due to implementation issues with BioShield. Again, unfortunately, that remains the case today.

Finally, HHS must learn from the set back in the VaxGen anthrax contract and not allow itself, or industry, to be deterred from this apparent failure by a single contractor. It is clear from the recent statements by Secretary Leavitt that HHS appears to be doing just that, and that is very encouraging. However, additional clarity and greater speed in implementing BioShield, along with the fast passage and implementation of BARDA, will provide industry with greater confidence in the long-term viability of the overall effort.

I close by noting that the proposals I have suggested have one thing in common - they do not require the appropriation of any additional dollars other than those that have already been passed or are proposed in the President's budget. While that may not appeal to you, Mr. Chairman, in your role as an Appropriations Cardinal, I suspect it may appeal to your views as Chairman of the Budget Committee. Thus, through changes in policy alone, we can make substantial progress in improving the Nation's preparedness for a pandemic or bioterrorist attack, as well as enhancing and protecting public health as a whole.

I very much appreciate the opportunity to offer testimony on this very important public health and anti-terrorism issue. Again, I applaud your efforts, and the efforts of President Bush and his Administration, and look forward to continuing our work with Congress and the Administration in this critical area.

I am happy to respond to any questions you may have.